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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ann Marie Schmidt, et al.

U.S. Serial No.: 09/689,469 Examiner: L.R. Helms

Filed : October 12, 2000 Group Art Unit: 1642

For : A METHOD FOR INHIBITING TUMOR INVASION OR  
SPREADING IN A SUBJECT

1185 Avenue of the Americas  
New York, New York 10036  
February 15, 2001

Assistant Commissioner for Patents  
Washington, D.C. 20231

SIR:

COMMUNICATION IN RESPONSE TO November 26, 2001  
OFFICE ACTION AND PETITION FOR A TWO-MONTH EXTENSION

This Communication is submitted in response to an November 26, 2001 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A Response to the November 26, 2001 Office Action was originally due December 26, 2001. Applicants hereby petition for a two-month extension of time. Applicants have previously established small entity status. The required fee for a two-month extension of time for a small entity is \$200.00 and applicants enclose a check to cover this fee. Therefore, a response is due February 26, 2002. Accordingly, this communication is being timely filed.

Restriction Requirement Under 35 U.S.C. §121

In response to this restriction requirement, applicant's undersigned attorney, on behalf of applicant, hereby elects, with traverse, to prosecute the invention of Examiner's Group III,

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i.e. claims 57-78, allegedly drawn to a method for identifying an agent which inhibits tumor invasion, classified in class 435, subclass 7.2.

✓ | Applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction of Examiner's Group III from Examiner's Groups I-II and IV be withdrawn in view of the fact that the claims of Examiner's Group III are not independent of Examiner's Groups I-II and IV. Applicant maintains that the claims of Examiner's Group III and Examiner's Groups I-II and IV do not define patentably distinct inventions.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The claims of Examiner's Group III, allegedly drawn to a method for identifying an agent which inhibits tumor invasion, are related to the claims of Examiner's Groups I-II and IV in that the claims in all groups are directly related to the inhibition of RAGE as part of their design, operation and effect.

The claims of Examiner's Group I, allegedly drawn to a method for inhibiting tumor invasion by administering soluble RAGE (sRAGE), are related to the claims of Examiner's Group II, allegedly drawn to a method for inhibiting tumor invasion by introducing into the subject a vector containing a nucleic acid,

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because both Examiner's Group I and Examiner's Group II use sRAGE to inhibit RAGE/ligand interactions. Therefore, applicants request that the Examiner examine Groups I and II on the merits.

The claims of Examiner's Group III, allegedly drawn to a method for identifying an agent which inhibits tumor invasion, are related to the claims of Examiner's Group IV, allegedly drawn to a method of inhibiting tumor invasion with an agent and a composition comprising the agent, because the agent and a composition comprising an agent of Examiner's Group IV are identified from the method of Examiner's Group III. Therefore, applicants request that the Examiner examine Groups III and IV on the merits.

The claims of Examiner's Group III, allegedly drawn to a method for identifying an agent which inhibits tumor invasion, are related to the claims of Examiner's Group I, allegedly drawn to a method for inhibiting tumor invasion by administering soluble RAGE, because of the reliance of all identified claims of Groups I and III on the specific inhibition of ligand binding to the highly conserved RAGE molecule as part of their design, operation, and effect. The specification recites that regarding tumor cell/extracellular matrix interactions "the Receptor to AGE (RAGE) interacts with a range of physiologically and pathophysiologically-relevant ligands." See page 21, lines 10-12. Further, the specification recites that "our studies indicate that interruption of cell RAGE-matrix (amphoterin and/or similar structures) is at least one mechanism by which

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sRAGE limits tumor growth. See page 22, lines 17-20. Therefore, Examiner's Group I, allegedly drawn to a method for inhibiting tumor invasion by administering soluble RAGE and Examiner's Group III, allegedly drawn to a method for identifying an agent which inhibits tumor invasion rely on the specific inhibition of ligand binding to the highly conserved RAGE molecule as part of their design, operation, and effect. Therefore, applicants request that the Examiner examine Groups I and III on the merits. Accordingly, Examiner's Groups I, II and IV are related to Group III through their respective relation to the claims of Group III.

Applicant therefore respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicant maintains that there would not be a serious burden on the Examiner if restriction were not required. A search of

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prior art with regard to Group III, claims 57-78 allegedly drawn to a method for identifying an agent which inhibits tumor invasion will reveal whether any prior art exists as to a method for inhibiting tumor invasion by administering a soluble RAGE (Group I), a method for inhibiting tumor invasion by introducing into the subject a vector containing a nucleic acid encoding soluble RAGE(Group II) and a method of inhibiting tumor invasion with an agent and a composition comprising the agent (Group IV). Since there is no burden on the Examiner to examine Groups I-IV in the subject application, the Examiner must examine the entire application on the merits.

Applicant maintains that claims 42-81 define a single inventive concept. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement and examine claims 42-81 on the merits.

In addition, applicants request that upon the allowance of a generic claim, consideration of claims to additional species which are written in dependent form be considered.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invite the Examiner to telephone him at the number provided below.

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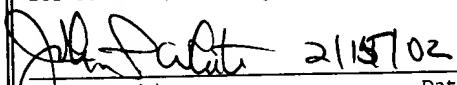
No fee other than the enclosed \$200.00 fee for a two-month extension of time, is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

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|-----------------|------|
| John P. White   | Date |
| Reg. No. 28,678 |      |